

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Epshtein et al.

Application No.: 10/522,653

Examiner: Szperka, M.

Filed: January 22, 2005

Group Art Unit: 1644

For: MEDICINAL AGENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR 1.132

I, O. I. Epshtein, Dr. Sc, do hereby declare as follows:

1. My name is Dr. Oleg I. Epshtein. I am the inventor of the '653 application.
2. The company I lead, Materia Medica Holdings, sells a product Afala for treatment of benign prostatic hyperplasia (BHP) and prostatitis.
3. Afala is covered by the above-identified application Ser. No. 10/522,653.
4. I am well familiar with the fields of pharmacology, homeopathy, physiology, and immunology. I authored over 100 articles in peer-reviewed journals.
5. While homeopathy was known and practiced for many years, I am not aware of any successful commercial product for treatment of BHP and/or prostatitis based on homeopathic technology.
6. Afala was launched in the year 2006. In the 6 months immediately following launch (first half of 2007), Afala achieved sales of 5,500,000 doses, which I consider a significant success for the Russian market. In the first 6 months of year 2008, Afala's sales were 17,000,000 doses, showing a significant growth over the year 2007 on per month basis. By this moment, total sales have reached 40,000,000 doses.
7. It is my opinion that the success of Afala is directly attributable to the merits of the technology claimed in the '653 application.

All statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment; or both, under Section 1001 of Title 18 of the U.S. Code and that such willful false statements may jeopardize the validity of any patent application issuing thereon.

A handwritten signature in dark ink, consisting of a stylized, cursive 'L' followed by a horizontal line that curves upwards at the end.

Dated: September 12, 2008